



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,028	10/25/2000	Jeffrey Olson	11926-112001	3430

26161 7590 05/16/2005

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
----------	--------------

1637

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/697,028	Applicant(s) OLSON ET AL.	
	Examiner Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' response to the office action filed on March 12, 2005 has been entered.

Status

2. Claims 10-16 are pending. Claims 1-9 are cancelled. All arguments have been fully considered and thoroughly reviewed, but are deemed persuasive for the reasons that follow. This action is made Non-Final.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitcombe et al. (USPN. 6,326,145).

Whitcombe et al. teach a method of claim 1, 16, for biasing (enriching desired nucleic acid) a DNA amplification reaction such that a first nucleic acid having a first nucleotide present at a polymorphic site (allele 1) is amplified to a greater extent than a second nucleic acid having a second, different nucleotide present at the polymorphic site (allele 2) (see col. 12, line 54-67, col. 13, line 1-52), said method comprising (a) contacting a sample of DNA with two amplification primers that hybridize to both the first and second nucleic acid molecule at locations that flank the polymorphic site, such that neither the first nor the second primer hybridizes to the polymorphic site (see col. 12, line 54-67, col. 13, line 1-20, col. 12, line 6-20,

Art Unit: 1637

fig. 11 and 13, indicating opposing primers forward and reverse primers that flank a target sequence); one of the two primers including a 5' portion which, when incorporated into an amplification product, will upon further amplification yield products that form a stable-stem-loop structure (see col. 7, line 49-67, col. 8, line 1-11, col. 9, line 2-24, indicate stem-loop structures formed when scorpion primers are used, Figs. 9, 11-12, indicating stem loop structures), the stem of which is perfectly matched and includes the polymorphic site only when the second nucleotide is present at polymorphic site (allele-specific) (see col. 9, line 2-24, col. 10, line 53-67, col. 11, line 1-17, col. 13, line 45-52);

(b) carrying out amplification, whereby the first nucleic acid molecule is amplified to a greater extent than a second nucleic acid molecule (see col. 13, line 15-63, col. 16, line 20-34).

With regard to claim 16, Whitcombe et al. teach step (c) determining the nucleotide sequence of at least a portion of the DNA present in the amplified DNA sample (see col. 13, line 45-63);

With regard to claims 11-12, 14-15, Whitcombe et al. teach that the DNA comprises single-stranded or double-stranded derived from mammalian (human cells) such as blood, bacteriophage, viruses (see col. 6, line 1-10);

With regard to claim 13, Whitcombe et al. teach that the method further comprises separately carrying out steps (a) and (b) for each of a plurality of polymorphic sites (see col. 10, line 53-59, indicating two-tube (plurality) ARMS test). Accordingly Whitcombe et al. meets the limitations in the instant claims.

Response to arguments

3. With regard to the rejection made under 35 USC 112, second paragraph, Applicants' arguments and the explanation for wild-type and mutant allele comprising nucleic acid molecules are fully considered and found persuasive. The rejection is withdrawn in view of the persuasive arguments.

4. With regard to the rejection made in the previous office action under 35 USC 102 (e), Applicants' arguments and the explanation for primers that flank a polymorphic site are fully considered and found persuasive. The rejection is withdrawn in view of the persuasive arguments.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

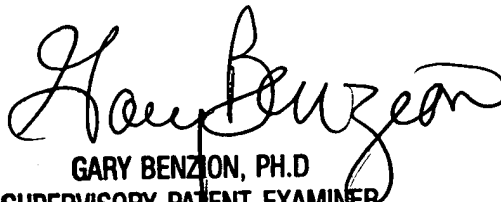
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Art Unit: 1637

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Examiner
Art Unit 1637


GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600